

REMARKS

This Amendment is being submitted in response to the Office Action dated July 5, 2007 in the above-identified application. Concurrently with this Amendment, Applicants submit a petition for a three-month extension of time for filing a response, along with the requisite fee and the authorization to charge our Deposit Account 50-0552 for any fee deficiencies. The time for filing a response to the July 5, 2007 Office Action is thereby extended to January 7, 2008, January 5, 2008 having fallen on a Saturday.

Claims 4 and 7-9 were pending in the case. By this response, those claims have been amended to present them in a better form, and new claims 10-13 have been added. Support for the amendments may be found, *inter alia*, on page 8, lines 16-17, page 12, lines 7-12, and page 12, lines 13-16 of the specification. No new matter has been introduced by the amendments. Applicants respectfully request their entry. Claims 4, 7-9 and 10-13 are now pending and under examination.

In view of the amendments made herein and the remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections and objections set forth in the July 5, 2007 Office Action.

COMPLIANCE WITH THE SEQUENCE REQUIREMENTS

The Office Action and the accompanying Notice to Comply state that the application fails to comply with the requirements of the sequence rules, as set forth in 37 CFR 1.821- 1.825, because it does not contain a paper copy and a computer readable form of the "Sequence Listing," and because "Figure 1 does not refer to any sequence identifiers for the sequence disclosed in the figure." See paragraphs 1-3 and 7 of the Notice to Comply.

In response, Applicants respectfully note that the paper copy of the Sequence Listing was submitted when the Application was filed, and a computer readable form was submitted on February 3, 2006 in response to the January 26, 2006 Notice of Defective Response. A copy of the earlier submissions are enclosed herewith.

Applicants further note that the “Brief Description of Drawings” section of the specification has been amended to incorporate the sequence identifiers to the sequences disclosed in Fig 1A and 1B.

In view of the foregoing, Applicants respectfully submit that the application complies with the requirements of the sequence rules (37 C.F.R. 1.821 -1.825).

CLAIM OBJECTIONS

Claims 4 and 7 to 9 were objected to for the use of the acronym “GHS-R” without first defining what it represents. Claims 4 and 7 to 9 have been amended to define the acronym GHS-R.

REJECTIONS UNDER 35 USC §112, FIRST PARAGRAPH

Claims 4 and 7-9 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and as failing to reasonably provide enablement to one of skill in the art to make/use the invention commensurate in scope with the claims.

The claims, as amended, are directed to a method of lowering the blood glucose level, a method of preventing or treating diabetes mellitus, a method of preventing or treating obesity, and a method of suppressing appetite. Each of said methods comprises administering an effective dose of a GHS-R antagonist selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3] –GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9,

Leu-11] substance P. The claimed methods using [D-Lys-3] –GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P are described and enabled by the specification, for example, page 23, line 18 to page 25, line 20. In addition, the specification fully supports the claimed methods using a ghrelin analog antagonist, which are described in detail on page 10, line 6 to page 12, line 6. The specification also provides clear guidelines on how to screen for a ghrelin analog antagonist (See, for example, page 8, lines 21-28). Therefore, those skilled in the art would be able to carry out the present invention without undue experimentation.

In view of the above, withdrawal of the rejections of claims under 35 U.S.C. 112, first paragraph, is respectfully requested

REJECTIONS UNDER 35 USC § 112, SECOND PARAGRAPH

Claims 4 and 7-9 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to recite that the GHS-R antagonist used therein is selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3] –GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P. The specification provides sufficient description regarding the use of said GHS-R antagonist for lowering blood glucose level, preventing or treating diabetes mellitus, preventing or treating obesity and suppressing appetite.

In view of the above, withdrawal of the rejections to the claims under 35 U.S.C. 112, second paragraph is respectfully requested.

REJECTIONS UNDER 35 USC §102

Claims 4 and 7-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1). Applicants respectfully traverse the rejections.

Claims 4 and 7-9, as amended, are directed to a method of lowering the blood glucose level, a method of preventing or treating diabetes mellitus, a method of preventing or treating obesity, and a method of suppressing appetite. Each of said methods comprises administering an effective dose of a GHS-R antagonist selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3] –GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P.

Andersen does not anticipate claims 4 and 7-9, at least because it does not disclose the claimed GHS-R antagonist. Anderson relates to the use of a ligand for the growth hormone secretagogue receptor type 1A (GHS-R 1A) for the regulation of food intake. See Andersen, page 1, paragraph [0001]. Andersen, however, does not disclose a GHS-R antagonist selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3] –GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P. Anderson also does not disclose the use of said GHS-R antagonist in lowering blood glucose level; preventing or treating diabetes mellitus; preventing or treating obesity; or suppressing appetite.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. 102(b) to claim 4 and claims 7 to 9 is respectfully requested.

CONCLUSION

In view of the amendments set forth herein and remarks above, Applicants respectfully submit that the pending claims are allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number provided.

Respectfully submitted,

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Ref. 480.1001US

January 5, 2005

Re: Application Transmittal of:
INUI et al.
Int. Appl. Serial No.: PCT/JP03/08482
Filed: July 3, 2003

CSK/jb

For: **THERAPEUTICS FOR DIABETES MELLITUS**

Enclosed Are:

- Certificate of Mailing by Express Mail (1 page)
- Transmittal Letter to the U.S. Designated/Elected Office Concerning a Filing Under 35 U.S.C. 371 (2 pgs);
- Copy of Int. Patent Application PCT/JP03/08482 (44 sheets);
- Translation of Int. Patent Application PCT/JP03/084820 (34 pgs);
- Fourteen (14) Sheets of Translated Drawings;
- Sequence Listing (paper copy) (4 pgs.);
- Preliminary Amendment (4 pgs);
- Unexecuted Declaration and POA (1 pg);
- Application Data Sheet (2 pgs): Letter re: Priority (1 pg.); and
- Check in the amount of \$300.00

WITH EXPRESS MAIL LABEL NO. EV 382 791 765 US

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Our Ref. 480.1001US

January 5, 2005

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